



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

T 2089M

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

HFI-35

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10/2/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-80

September 23, 1998

Donnie W. Wilson, President
Wilson Seafresh Seafood, Inc.
P.O. Box 489
Apalachicola, FL 32320

Dear Mr. Wilson:

During an inspection of your plant located at 401 Market Street, Apalachicola, Florida, on July 14, 1998, our investigator documented violations of Section 402(a)(4) and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (The Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products", (Seafood HACCP Regulation), as follows:

Your HACCP plan has not been adequately implemented as required by 21 CFR 123.6(b) in that you have chosen receipt of packaging as the critical control point for the control of the hazard of undeclared sulfites and:

- 1) have not identified or applied an appropriate critical limit for packaging as specified in 21 CFR 123.6(c)(2), e.g., presence of the sulfite declaration on each package;
- 2) have failed to implement adequate monitoring procedures in the HACCP plan for the chemical hazard of undeclared sulfites. As an indication of this failure, our investigator found finished, packaged product with undeclared sulfites; and
- 3) have not provided for recordkeeping as specified in 123(6)(c)(7) for the monitoring of the sulfite declaration at the critical control point.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.


FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,


Douglas D. Tolen
Director, Florida District